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EXAMINER	
WOO, JULIAN W	

ART UNIT	PAPER NUMBER
3773	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/726,135	ROSENBLUTH ET AL.	
	Examiner	Art Unit	
	Julian W. Woo	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *79-106 and 111-140* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *79-106 and 111-140* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

.*Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 79-81, 84-87, 90, 92-96, 101-106, 114-116, and 118-140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wholey et al. (2002/0169497) in view of Abolfathi et al. (5,786,679), and further in view of Rhee et al. (5,308,889).

Wholey et al. disclose, at least in figures 7 and 24 and in paragraphs [0045] and [0050] to [0052], the invention substantially as claimed. Wholey et al. disclose a method for preventing leakage into a perigraft space (14) between an endovascular graft (e.g., 28) and an adjacent portion of an aneurysmic blood vessel wall, a method of treating a vessel within a body, and a method of treating an aneurysm of a vessel, where the methods include a device or expansile material comprising a solid member (36) having expansile polymeric material (e.g., gel, organic elastomers, and polymeric foams)

disposed thereon is provided, a flexible cannula (32) or a delivery device is inserted into the lumen of the blood vessel or positioned in proximity of a target location within the vessel; where the graft is expanded at the target location such that a perigraft space is formed, where the device is introduced through the cannula and into a perigraft space between the endovascular graft and the blood vessel wall or the aneurysm. However, Wholey et al. do not disclose that disposing the endovascular graft over a distal end of the cannula and over the adjacent portion of the blood vessel wall such that the distal end of the cannula is positioned between the external surface of the endovascular graft and a wall of the blood vessel that mates with the external surface of the endovascular graft, pressing the distal end of the delivery device between an external surface of the graft and internal surface of the vessel, or positioning the cannula between an outside surface of the graft and an inside surface of the vessel wall, and Wholey et al. do not disclose that the expansile polymeric material is substantially in a non-expanded state when it is introduced into the perigraft space through the cannula and allowed to expand to an expanded state in the perigraft space. Wholey et al. also do not disclose that the total volume of non-expanded expansile polymeric material is predetermined before its expansion in the perigraft space. Wholey et al. do not disclose that the expansile material is a hydrogel, or that the solid member is in the form of an elongate member or a coil, or is formed of platinum or wire. Abolfathi et al. teach, in figures 4 and 7 and in col. 5, line 56 to col. 6, line 18; col. 7, lines 16-39; and col. 8, line 56 to col. 9, line 12; disposing an expandable endovascular device (20) or graft (90) over the distal end of a cannula (65) or delivery device and over an adjacent portion of a blood vessel wall such

that the distal end of the cannula is positioned between an external surface of the endovascular device or graft and the wall of the blood vessel that mates with the external surface of the endovascular device or graft. Abolfathi et al. also teach an expansile polymeric material (e.g., hydrogel) that is introduced through a cannula in a non-expanded state allowed to expand to an expanded state in an aneurysmic space, and Abolfathi et al. teach coils as an expansile material, as well a solid member formed of platinum coils or wires. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Abolfathi et al., to modify the method of Wholey et al., so that the cannula is positioned as claimed, and such that expansile material as claimed in applied. A cannula as applied by Abolfathi et al. would not only be useful for introducing expansile material into an aneurysmic space, it may be used to aspirate part of the volume of the space and thereby reduce the size of the aneurysm from its untreated condition without having to penetrate a graft wall or a blood vessel wall. It also would have been obvious to one having ordinary skill in the art to predetermine the total volume of non-expanded expansile polymeric material to be deployed in the perigraft space. Such a predetermination would allow the selection of an appropriate size for the device, so that it would expand and fill the perigraft space that has been sized. Also, introducing an expansile material through a cannula in an unexpanded state and allowing the material to expand to an expanded state in an aneurysmic space would ease insertion of the material through a small-diameter cannula and allow controlled placement of the material within the space. Also, it would be obvious to one having ordinary skill in the art, in view of Abolfathi, to apply hydrogel

or coils in the method of Wholey et al. A hydrogel can harden and/or swell in order to close off an aneurysmic cavity, while coils can induce thrombosis of blood within the cavity. A platinum coil would allow fluoroscopic imaging of the solid member and the surgical site. Wholey et al. in view of Abolfathi et al. also do not disclose that the polymeric material expands to its expanded state in an environment having a pH of about 7.4 or as the pH of the environment increases. (Abolfathi et al. teach hardening of a hydrogel or polymer according to pH; i.e., the hydrogel is pH-sensitive). Nevertheless, it would have been obvious to one having ordinary skill to apply a material so that it expands at a pH of about 7.4 or as the pH of the environment increases, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

However, Wholey et al. in view of Abolfathi et al. also do not disclose that the expansile polymeric material is previously physically compressed to a first pellet size and set in the non-expanded state or previously squeezed to a desired size and set at the desired size, or in the form of pellets or is filamentous, where the expansile material is set, squeezed, or compressed as claimed. Rhee et al. teach, at least in col. 10, lines 35-65; col. 12, lines 1-9, and col. 13, lines 27-52, an expansile polymeric material that is previously physically compressed or squeezed (i.e., extruded by a fixture or “extrusion device”), dehydrated (i.e., dried with heat) and cut to a first pellet size or desired size or is in the form of pellet or small filaments (i.e., "small pieces" or "very small pieces") and set in a non-expanded state and size. The pellets are then implanted in a patient's body, where the polymeric material expands. It would have been obvious to one having

ordinary skill in the art at the time the invention was made, to physically compress the expansile polymeric material as claimed. Such a practice would allow the convenient dosing and delivery (through a minimally-invasive cannula or syringe) of the polymeric material to a perigraft space or aneurysm, where the pellets or filamentous material can expand and fill every corner of the space or aneurysm.

Wholey et al. in view of Abolfathi et al. and Rhee et al. do not disclose that the solid member is formed of polyvinyl alcohol filament. Nevertheless, it has been held to be within the general skill of a worker in the art to select a known material on the basis for its suitability for its intended use as a matter of design choice.

. Wholey et al. in view of Abolfathi et al. and Rhee et al. do not disclose/teach the pore size or porosity of the polymeric material as claimed. Nevertheless, it has been held that discovering an optimum value of a result effective variable (pore size or porosity) involves only routine skill in the art.

Wholey et al. in view of Abolfathi et al. and Rhee et al. do not disclose that the cannula comprises a plastic tube. Nevertheless, it has been held to be within the general skill of a worker in the art to select a known material on the basis for its suitability for its intended use as a matter of design choice.

Finally, Wholey et al. in view of Abolfathi et al. and Rhee et al. do not disclose performing the method after detection of an endoleak. Nevertheless, it would have been obvious to one having ordinary skill in the art to perform the method after detection of the endoleak in order to pinpoint the leak, embolize the located site, and prevent future leakage.

3. Claims 82 , 83 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wholey et al. (2002/0169497) in view of Abolfathi et al. (5,786,679) and Rhee et al. (5,308,889), and further in view of Irie (5,891,155). Wholey et al. in view of Abolfathi et al. and Rhee et al. disclose the invention substantially as claimed, but the combination does not disclose that the expansile polymeric material is radiopaque or radiopaque by the incorporation of radiopaque monomers. Irie teaches, in col. 5, lines 36-46, polymeric material that is radiopaque or radiopaque by the incorporation of radiopaque material. Thus, it would have been obvious to modify the expansile polymeric material of the device of Wholey et al. in view of Abolfathi et al. and Rhee et al., so that is radiopaque. Radiopacity would allow visualization of the device by conventional imaging techniques. It would also be obvious to one having ordinary skill in the art to apply radiopaque monomers as radiopaque material in the polymeric material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis for its suitability for its intended use as a matter of design choice.

Additionally, Wholey et al. in view of Abolfathi et al. and Rhee et al. do not disclose that the device is initially attached to a delivery member by way of a detachable connection. Irie teaches, in figures 2 and 3 and in col. 3, line 63 to col. 4, line 48; a device (24) that is initially attached to a delivery member (36) by way of detachable connection (22). It would have been obvious to one having ordinary skill to modify the device of Wholey et al. in view of Abolfathi et al. and Rhee et al., so that it has the characteristics of the device and delivery member as taught by Irie. Such a device and

a delivery member would ease deployment of the device into the perigraft space and allow rapid separation of the device from the delivery member and the cannula.

4. Claims 88, 89, and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wholey et al. (2002/0169497) in view of Abolfathi et al. (5,786,679) and Rhee et al. (5,308,889), and further in view of Gia (5,690,667). Wholey et al. in view of Abolfathi et al. and Rhee et al. disclose the invention substantially as claimed, where the solid member may comprise coils (See also Rhee et al., col. 33 lines 18-46). However, the combination does not disclose a plurality of pieces of polymeric material disposed at spaced-apart locations on an elongate solid member, where the device comprises coil spacers between pieces of polymeric material, and where the solid member is formed of platinum and tungsten. Gia teaches, in figures 1-4 and in col. 2, lines 43-50 and col. 3, lines 6-18; a solid member (10) including a plurality of pieces of polymeric material (17) disposed at spaced-apart locations on an elongate solid member, where the member comprises coil spacers (11) between the pieces of polymeric material, and where the solid member (at 11) is formed of platinum and tungsten. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Gia, to modify the device of Wholey et al. in view of Abolfathi et al. and Rhee et al., so that it is configured as claimed. Such a modification would not only facilitate embolization of a perigraft space or aneurysm and fluroscopic visualization of the device and surgical site, the modified solid member would have blunted ends that would reduce the likelihood of abrasion or puncture of a blood vessel by a metal coil.

5. Claims 79, 96-99, and 117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smalling (6,730,119) in view of in view of Abolfathi et al. (5,785,679), and further in view of Rhee et al. (5,308,889). Smalling discloses, at least in figures 1A and 6A and in col. 14, line 40 to col. 15, line 27; the invention substantially as claimed. Smalling discloses a method for preventing leakage into a perigraft space (305) between an endovascular graft (1100) and an adjacent portion of an aneurysmic blood vessel wall and a method of treating a vessel within a body, where the methods include a device or expansile material comprising a solid member (310) having expansile polymeric material (e.g., coils, foam, and gel) disposed thereon is provided, where the a cannula (410) or delivery device is inserted into the lumen of the blood vessel or positioned in proximity of a target location within the vessel, where the device or expansile material is introduced through the cannula or delivery device and through a catheter or microcatheter (400), and into the perigraft space; where the cannula is also advanced through a hollow needle (192) in tissue of a patient's body. However, Smalling does not disclose disposing the endovascular graft over a distal end of the cannula and over the adjacent portion of the blood vessel wall such that the distal end of the cannula is captured between the external surface of the endovascular graft and a wall of the blood vessel that mates with the external surface of the endovascular graft, and Smalling does not disclose that the expansile polymeric material is in a non-expanded state when it is introduced into the perigraft space through the cannula and allowed to expand to an expanded state in the perigraft space. Abolfathi et al. teach, in figures 4 and 7 and in col. 5, line 56 to col. 6, line 18; col. 7, lines 16-39; and col. 8, line

56 to col. 9, line 12; disposing an endovascular device (20) or graft (90) over the distal end of a cannula (65) or delivery device and over an adjacent portion of a blood vessel wall such that the distal end of the cannula is captured between an extemal surface of the endovascular device or graft and the wall of the blood vessel that mates with the external surface of the endovascular device or graft. Abolfathi et al. also teach an expansile polymeric material (e.g., hydrogel) that is introduced through a cannula in a non-expanded state allowed to expand to an expanded state in an aneurysmic space. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Abolfathi et al., to modify the method of Smalling, so that the cannula is captured as claimed, and such that expansile material as claimed is applied. A cannula as applied by Abolfathi et al. would not only be useful for introducing expansile material into an aneurysmic space, it may be used to aspirate part of the volume of the space and thereby reduce the size of the aneurysm from its untreated condition without having to penetrate a graft wall or a blood vessel wall. Also, introducing an expansile material through a cannula in an unexpanded state and allowing the material to expand to an expanded state in an aneurysmic space would ease insertion of the material through a small-diameter cannula and allow controlled placement of the material within the space. Smalley also does not disclose that the microcatheter has a lumen of .005-050 inch in diameter. Nevertheless, it would have been a matter of obvious design choice to one having ordinary skill in the art at the time the invention was made to size the lumen as claimed, since such a modification would

have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

However, Smalling in view of Abolfathi et al. does not disclose that the expansile polymeric material is previously physically compressed and set in the non-expanded state. Rhee et al. teach, at least in col. 10, lines 35-65 and col. 12, lines 1-9, an expansile polymeric material that is previously physically compressed (i.e., extruded), dehydrated, and cut to a first pellet size (i.e., "small pieces" or "very small pieces") and set in a non-expanded state. The pellets are then implanted in patient's body, where polymeric material expands. It would have been obvious to one having ordinary skill in the art at the time the invention was made, to physically compress the expansile polymeric material as claimed. Such a practice would allow the convenient dosing and delivery (through a minimally-invasive cannula or syringe) of the polymeric material to a perigraft space or aneurysm, where the pellets can expand and fill every corner of the space or aneurysm.

6. Claims 111 and 113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wholey et al. in view of Abolfathi et al. and Rhee et al. as applied to claim 79 above, and further in view of Goupil et al. (6,676,971). Wholey et al. in view of Abolfathi et al. disclose the invention substantially as claimed, but do not disclose that the cannula is rigid or comprises a metal tube. Goupil et al. teach, in col. 18, lines 41-63, accessing a perigraft space with a cannula (a catheter or a syringe) for delivery of an embolic device, where the distal end of the cannula may be advanced through a patient's body (e.g., a patient's back) and through the wall of the blood vessel adjacent

to the graft and into the perigraft space. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Wholey et al. in view of Abolfathi et al. and Rhee et al., such that a substantially rigid cannula or a cannula formed of a metal tube is applied, since such a cannula would allow penetration of tissue for access to the perigraft space. Moreover, it is held to be within the general skill of a worker in the art to select a known material (e.g., a rigid or metal material) on the basis of its suitability for the intended use as a matter of obvious design choice.

Response to Amendment

7. With respect to arguments regarding the rejection based on the Greene, Jr. et al. patent: A declaration of George R. Greene, Jr., under 37 CFR Section 1.132, and as mentioned in the Applicant's remarks, was not received by the Office. Nevertheless, Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773